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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,643	04/20/2001	Gad Keren	34948	2139

67801 7590 12/16/2008

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EXAMINER	
NGUYEN, CAMTU TRAN	
ART UNIT	PAPER NUMBER
3772	
MAIL DATE	DELIVERY MODE
12/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/839,643	KEREN ET AL.	
	Examiner	Art Unit	
	Camtu T. Nguyen	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-51,59-84 and 86-112* is/are pending in the application.

4a) Of the above claim(s) *62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-51,59-61,63-84 and 86-112* is/are rejected.

7)☒ Claim(s) *87,88,93-95 and 97* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11-5-2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 9-24-2008 has been entered.

Claims 59-61, 63, 67, 68, 70, 72, 73, 80-82, 84, 92, 93, 103, 105, and 109 have been amended.

Applicant's comments directed to the prior arts applied in the previous Office Action are acknowledged and deemed persuasive, particularly to method claims. Thus, the rejections of those prior arts have been withdrawn from the method claims. Clearly, prior arts do not teach the method of decreasing blood pressure in a heart by an implanted shunt positioned between the left atrium & the right atrium.

The claims, as amended, have been carefully considered but they are not allowable in view of the following rejection(s).

Claim Objections

Claims 87, 88, 93-95, and 97 are objected to because they recite "a valve", is this valve different from or same as the valve of claim 84? Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49-50 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationship between the valve element (claim 49) and the fixation elements of the tubular element (claim 50).

Claim 75 recites the limitation "the conditions" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 49 & 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the steps recited in these claims would not decrease blood pressure in the heart, thus, rendering these claims incomplete & inadequate to perform the limitations in the preamble.

Claim 89 recites the limitation "the right ventricle" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 49-51, 59-61, 63-71, 73, 74, 76-79, 84, 86-87, 89, 90, 92, 98-102, 111, and 112 are rejected under 35 U.S.C. 102(e) as being anticipated by Bailey et al (U.S. Patent No. 6,458,153). Bailey et al discloses in Figures 7-11 a stent valve (40) in the chamber-to-chamber (CC) configuration, the CC stent valve (40) comprising a valve (28) which opens allowing blood to flow through the stent valve (40) upon a pressure differential therebetween and would close by zero pressure differential therebetween (column 10 lines 45-67 & column 11 lines 1-12).

With regards to claim 49, 59, 84, 111, and 112, Bailey et al discloses the CC stent valve (40) of Figures 7-11 may be delivered into a position to repair septal defects which commonly referred to atrium-to-atrium or to ventricle-to-ventricle. Clearly, the Bailey et al reference discloses applicant's claimed invention.

With regards to claim 79, Figure 10 illustrates the valve (28) including flat pivoting flap (26).

With regards to claim 92, when the Bailey et al stent valve device (10) is positioned in (CC) configuration, specifically, the atrium-to-atrium, the device (10) would allow for blood flow during diastole cycle.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 49 & 50 are rejected under 35 U.S.C. 102(b) as being anticipated by King et al (U.S. Patent No. 3,874,388).

King et al discloses a shunt implanted between a left atrium and a right atrium, thus, the King et al would perform the steps recited in these claims.

With regards to the valve and the fixation member, specifically for these structures to be entitled to weight, such structural limitations must affect the method in a manipulative sense and not mount to mere claiming of use of their structure. Ex Parte Pfeiffer 782 OG 639, 1962 CD 408.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 72, 75, 80-83, 88, 91, 93-97, 103, 110, rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al (U.S. Patent No. 6,458,153) in view of Wolf et al (U.S. Patent No. 6,641,610).

Bailey et al discloses in Figures 7-11 a stent valve (40) in the chamber-to-chamber (CC) configuration, the CC stent valve (40) comprising elements in these claims but does not teach a sensor and a controller as recited in claims 97 & 103.

Wolf et al discloses in Figure 7 shunt conduit (34) comprising a valve (32) operative in conjunction with a sensor (30) senses/detects the signal output produced from the heart muscle and an actuator (36) opens the valve (32) based on the reading of the sensor (30).

Therefore, it would have been obvious to one of ordinary skilled in the art to utilize the sensor (30) & the controller (36), taught by Wolf et al, with Bailey et al's stent valve (40) as such would regulate the stent valve (40) in order to prevent any potential back flow in the heart atria.

With regards to claims 81-83, the Wolf et al discloses a display in the form of an electrocardiogram machine indicating the heart activities, thus, indicting the condition of the valve involved.

With regards to claims 72, 75, and 80, Wolf et al discloses a hydrodynamic/electric pump (column 7 lines 4-7), for controlling the valve, of which is well known in the art to be outside of the patient's body.

With regards to claim 88, Wolf et al discloses a hydrodynamic/electric pump (column 7 lines 4-7), for controlling the valve et al valve would open to relief pressure built in the atrium flow when pressure is above 12 mmHg.

With regards to claim 91, it would have been obvious to one of ordinary healthcare professional to notify the physician updating him/her any changes in the patient's condition, including the situation of the valve.

With regards to claim 93-96, Wolf et al discloses a hydrodynamic/electric pump (column 7 lines 4-7), for controlling the valve. The pump would inherently have a power source in order to the pump to operate.

Claims 104-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al (U.S. Patent No. 6,458,153)/Wolf et al (U.S. Patent No. 6,641,610), presented above, and further in view of Cosman (U.S. Patent No. 4,787,886).

Bailey et al/Wolf et al, presented above, discloses a stent valve (40) in the chamber-to-chamber (CC) configuration, the CC stent valve (40) comprising elements in these claims including a sensor and a controller but does not teach the sensor comprises a pressure.

Cosman discloses a shunt valve system comprising a pressure sensor. Therefore it would have been obvious to one skilled the art to use the sensor that senses/detects a pressure, taught by Cosman in place of Bailey et al's sensor for purposes of sensing/detecting a pressure in the patient's heart.

With regards to claims 106-108, the Bailey et al valve would open to relief pressure built in the atrium flow when pressure is above 20 mmHg, a pressure mark that is considered high for diastole cycle.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772